

“BZMP” JSC			
Raw material specification		SPS-KO-14-0248-08 (CIIC-KO 14-0248-08)	
		Page 1 of 3	
Effective date: /Date/	Supersede: SPS-KO-14-0248-07 (CIIC-KO 14-0248-07) dated 19.04.2016	Valid until: <u>unlimited</u>	Reason: update

POVIDONE IODIZED
Povidonum iodinum
POVIDONE IODINE

Quality control according to Normative Documentation ND RB 0617C-2016 (HД ПБ 0617C-2016)

Prepared by	Agreed by:	Approved by
Position: Chemist of the II category of Analytical Laboratory	Position: Head of Quality Control Department	Position: Deputy Director General for Quality
Full name: M.V. Babzhantseva	Full name: O.V. Zenko	Full name: T.V. Baturо
Signature: /Signature/	Signature: /Signature/	Signature: /Signature/
Date: /Date/	Date: /Date/	Date: /Date/
Position: Microbiologist of the II category	Position: Deputy Head of Analytical Laboratory	
Full name: V.O. Ratnikova	Full name: N.A. Malygina	
Signature: /Signature/	Signature: /Signature/	
Date: /Date/	Date: /Date/	
	Position: Head of Microbiological Laboratory	
	Full name: S.V. Golovkova	
	Signature: /Signature/	
	Date: /Date/	
	Position: Head of Standardization and Registration Department	
	Full name: O.V. Gospodynich	
	Signature: /Signature/	
	Date: /Date/	
	Position: Head of Procurement Department	
	FULL NAME. V.V. Latogursky	
	Signature: /Signature/	
	Date: /Date/	

“BZMP” JSC				
Raw material specification			SPS-KO-14-0248-08 (CIIC-KO 14-0248-08)	
			Page 2 of 3	
S. No.	Control parameters	Methods	Test methods	Acceptance criteria
1	Use			Povidone-iodine, ointment for external use 100 mg / g
2	Quality parameter name: 2.1 Appearance (properties) 2.2 Identification A. IR spectrum B. Qualitative reaction C. Qualitative reaction 2.3 pH 2.4 Iodides 2.5 Loss on drying 2.6 Sulphated ash 2.7 Residual amount of organic solvents: - 2-propanol 2.8 Heavy metals 2.9 Nitrogen content 2.10 Assay of iodine	Visual State Pharmacopoeia of the Republic of Belarus II, volume 1, p. 21 State Pharmacopoeia of the Republic of Belarus II, volume 1, 2.2.24 In accordance with the Normative Documentation In accordance with the Normative Documentation State Pharmacopoeia of the Republic of Belarus II, volume 1, 2.2.3 In accordance with the Normative Documentation State Pharmacopoeia of the Republic of Belarus II, volume 2, 2.2.32 State Pharmacopoeia of the Republic of Belarus II, volume 1, 2.4.14 State Pharmacopoeia of the Republic of Belarus II, volume 1, 2.4.24, 2.2.28 State Pharmacopoeia of the Republic of Belarus II, volume 1, 2.4.8, method C In accordance with the Normative Documentation Titrimetric	SOP-KO-14-102 (COII-KO-14-102) State Pharmacopoeia of the Republic of Belarus II, volume 1, 5.11 Section “Identification A” Normative Documentation ND 0617C-2016 (HД PБ 0617C-2016) Section “Identification B” Normative Documentation ND 0617C-2016 (HД PБ 0617C-2016) Section “Identification C” Normative Documentation ND 0617C-2016 (HД PБ 0617C-2016) Section “pH” Normative Documentation ND 0617C-2016 (HД PБ 0617C-2016) Section “Iodides” Normative Documentation ND 0617C-2016 (HД PБ 0617C-2016) Section “Loss on drying” Normative Documentation ND 0617C-2016 (HД PБ 0617C-2016) Section “Sulphated ash” Normative Documentation ND 0617C-2016 (HД PБ 0617C-2016) Section “Residual organic solvents” Normative Documentation ND 0617C-2016 (HД PБ 0617C-2016) Section “Heavy Metals” Normative Documentation ND 0617C-2016 (HД PБ 0617C-2016) Section "Nitrogen Content" Normative Documentation ND 0617C-2016 (HД PБ 0617C-2016) Section “Assay” of Normative Documentation ND RB 0617C-2016 (HД PБ 0617C-2016)	Yellowish-brown or reddish-brown amorphous powder. Soluble in water and alcohol. Practically insoluble in acetone A. The IR absorption spectrum of the test sample corresponds to the spectrum of povidone iodinated CO (EP CRS) or the spectrum shown in Fig. 1 B. Dark blue coloration appears C. A light brown precipitate is formed 1.5 to 3.5 Not more than 6.0%, calculated on an anhydrous basis Not more than 8.0% Not more than 0.025% State Pharmacopoeia of the Republic of Belarus II, volume 2, 5.4 Not more than 5000 ppm Not more than 0.001% (10 ppm) 9.5% to 11,5%, on an anhydrous basis Not less than 9.0% and not more than 12.0%, calculated on an anhydrous basis

/Signature/

“BZMP” JSC				
Raw material specification			SPS-KO-14-0248-08 (CIIC-KO 14-0248-08)	
			Page 3 of 3	
S. No.	Control parameters	Methods	Test methods	Acceptance criteria
	2.11 Microbiological quality: - Total Aerobic Microbial Count (TAMC) and Total Yeast and Mould Count (TYMC), in total - bile-tolerant gram-negative bacteria or bacteria of the <i>Enterobacteriaceae</i> family - <i>Pseudomonas aeruginosa</i> - <i>Staphylococcus aureus</i>	State Pharmacopoeia of the Republic of Belarus II, volume 1, 2.6.12, 2.6.13	Method of suitability AM-12-0248 Validation Protocol MMV-MI-12-084 (MMV-MH-12-084)	State Pharmacopoeia of the Republic of Belarus II, volume 1, 5.1.4 Not more than 10 ² CFU/g Absence in 1 g Absence in 1 g Absence in 1 g
3	Sampling	-	In accordance with the standard operating procedure: SOP-KO-12-024 (COП-KO-12-024); SOP-KO-14-057 (COП-KO-14-057)	-
4	Control sampling volume	-	-	Analytical laboratory: 28.0 g Microbiological laboratory: 10.0 g
5	Storage conditions	-	-	In a dark place
6	Expiry date	-	-	3 years
7	Packaging	-	-	Polyethylene jars, as well as other types of packaging, ensure the preservation of raw materials throughout the shelf life.
8	Manufacturer	-	-	BASF Corporation, USA
9	Code	-	-	120158